SMA

Microbial Air Sampler System
Product Guide

© Copyright, June 1998, All rights Reserved.

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

Table of Contents

Section 1: Welcome to ECMD
Section 2: SMA Atrium
Section 3: SMA Remote Sampler
Section 4: SMA Compressed Air Sampler
Section 5: SMA MicroPortable P100 & P200
Section 6: SMA Control Centers 1-10 Locations
Section 7: SMA OneTouch Command System
Section 8: SMA ISO-CC Control Centers 1-10 Locations
Section 9: Ordering SMA Products (complete guide)

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

Section 1:
Welcome to ECMD

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

WELCOME TO ECMD:
Environmental Control Monitoring Division

VAI's Environmental Control Monitoring Division (ECMD) has addressed the needs of the Pharmaceutical, Biotechnology, Semi-Conductor, and Electronics industries by designing a complete range of air testing equipment. ECMD products are designed to test for the presence of microbial and particulate contaminants within air and on products deemed suitable for clean room operations.

VAI's ECMD manufactures the SMA Microbial Air Sampler Systems, The Helmke-Yeich (H-Y) Tumble Drum Tester and the VTC Variable Temperature Controller.

The SMA Microbial Air Sampler Systems are designed to test air within the clean room setting to determine the level of viable contamination that is present. The SMA Microbial Air Sampler Systems have been used for over 14 years by pharmaceutical and biotechnology organizations, worldwide. The SMA Micro Sampler Systems offer a complete range of products to meet all requirements for quantitative microbial air evaluation. The SMA Systems include the SMA Atrium, SMA Remote Sampler, SMA Compressed Air Sampler, SMA "CC" Facility Control Centers, SMA ISO-CC Isolator Control Centers and the SMA MicroPortable.

The SMA Atrium and Facility Control Centers with OneTouch Command Systems features afford the ability to test multi-locations either simultaneously or independently. Outlined in the pages to follow, the SMA Micro Sampler Systems and SMA One Touch Command Systems are available in models that test from one (1) to ten (10) locations. The SMA ISO-CC Isolator Control Centers are designed for use with isolation barriers systems and incorporate OneTouch Command System features for testing 1 to 10 locations simultaneously or independently.

The SMA product line also includes the SMA MicroPortable and the SMA Compressed Air Sampler. The SMA MicroPortable is a battery-operated unit that can sample for 8 hours continuously. The SMA Compressed Air Sampler is designed as a portable sampler to assist in delineating the microbial levels of compressed air and gas systems.

ECMD also manufactures the H-Y Tumble Drum Tester. The H-Y-Tumble Drum Tester is a recommended method for testing and disseminating the inherent contamination levels of products deemed suitable for the controlled environment by the Institute of Environmental Sciences RP3 (4).

ECMD's VTC Controller provides for the evaluation of possibly existent particulate within a volume of air from high temperature applications such as ovens and tunnels up to 1250^{o}F. The SMA products are described on the pages to follow. Please contact VAI for additional product information at 1-888-4-STERILE.

Section 2:
SMA Atrium

SMA-316-25-1/2

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA Atrium

For over 15 years, the SMA Atrium has been the chosen test method of many pharmaceutical and biotechnology organizations for determining the level of existent microbial contaminants in their manufacturing operations.

SMA Atrium is a unique microbiological air sampler that can be completely sterilized via steam, heat or ETO. Constructed of anodized aluminum, 304 stainless steel or 316L stainless steel, the Atrium is very durable and needs little maintenance. The Atrium is sized at 4 1/2" in diameter by 1 1/2 inches in height. This compact size of the unit provides the opportunity to locate the sampling device near filling processes where space is limited. The small size of the unit coupled with its simplistic operation has enabled many operations to report accurately the air quality near fill areas and reduce false positives from operators.

Air Flow and Media Usage

The SMA, operating at an air flow of 1 cubic foot per minute (1 CFM), has been designed to provide a tortuous path that air must travel and assures a 95% capture efficiency of 0.5 micron particles and larger. The integration of 12 top orifices that are available in 1/2", 1/4" and 3/32" provide the user the ability to sample for varying time periods. Time periods can extend up to 4 hours on one plate. Top orifice size is dependent upon the desired exposure time versus desiccation of the nutrient media. The use of the 3/32" top orifices allows a maximum 60 minute exposure time, while the 1/4" and 1/2" allow up to 4 hours (dependent upon conditions).

The SMA Atrium utilizes a 100 mm plate filled to either 25 ml. or 32 ml. of nutrient media. These fill levels are standard from most suppliers and each level delineates a unique sampling condition. The use of the SMA 25 ml. fill unit provides the user the ability to sample up to 90 minutes on one agar plate. The SMA 32 ml. fill unit increase possible sampling time to 4 hours on one agar plate.

Operation of the Unit

The SMA Atrium requires only a vacuum source to operate. Vacuum options can include either central vacuum systems or one of the VAI 1-10 location control centers.

Order #	Top Orifice Choice	Atrium Description
SMA-AA-25 or 32	1/2", 1/4" or 3/32"	Anodized Aluminum 25 ml or 32 ml. fill level
SMA-304-3/32-25 or 32	1/2", 1/4" or 3/32"	304 Stainless 25 ml or 32 ml. fill level
SMA-316-3/32-25 or 32	1/2", 1/4" or 3/32"	316 Stainless 25 ml or 32 ml. fill level
SMA-WALLATR	N/A	Atrium Wall Bracket (removable)

(Specify top orifice size when ordering. The ½" orifice is standard)

Available Technical Data Supplements (Upon Request)

SMA-3001: SMA Atrium Validation Report
SMA-3002: SMA Atrium User Manual

Section 3:
SMA Remote Sampler

SMA-316-RE-25

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA Remote Atrium

In some instances the use of the SMA Remote Atrium may be necessary when the size of the SMA Atrium, while small, may be too large to fit into a location deemed critical to be tested for microbial contaminants.

The SMA Remote Atrium is designed with one extension tube protruding from the top. This tube may serve as a connection point for either disposable tubing or stainless steel connections. By use of the SMA Remote SMA Remote Atrium, a user can locate the Atrium away from the point of sample.

The SMA Remote Atrium can be completely sterilized via steam, heat or ETO. Constructed of either 304 or 316L stainless steel, the Atrium is very durable and needs little maintenance. The Atrium is sized at 4 1/2" in diameter by 1 1/2 inches in base height with an extension tube for tubing connection on top of the unit. This compact size of the unit provides the opportunity to locate the sampling device near filling processes where space is limited. The small size of the unit coupled with its simplistic operation has enabled many operations to more accurately report air quality near fill areas and reduce false positives from operators.

Air Flow and Media Usage

The SMA Remote, operating at an air flow of 1 cubic foot per minute (1 CFM), has been designed to provide a tortuous path that air must travel and assures a 95% capture efficiency of 0.5 micron particles and larger. The SMA Remote Atrium integrates a 3/8" ID connection that easily attaches to presterilized tubing.

The SMA Remote Atrium utilizes a 100 mm plate filled to either 25 ml. or 32 ml. of nutrient media.

These fill levels are standard from most suppliers and each level delineates a unique sampling condition. The use of the SMA 25 ml. fill unit provides the user the ability to sample up to 60 minutes on one agar plate. The SMA 32 ml. fill unit increase possible sampling time to 2 hours on one agar plate.

Operation of the Unit

The SMA Remote Atrium requires only a vacuum source to operate. Vacuum options can include either central vacuum systems or one of the VAI 1-10 location control centers.

Order #	Remote Atrium Description
SMA-304-RE-25 or 32	304 Stainless 25 ml. or 32 ml. fill level
SMA-316-RE-25 or 32	316 Stainless 25 ml. or 32 ml. fill level

Available Technical Data Supplements (Upon Request)

SMA-3001: SMA Atrium Validation Report
SMA-3002: SMA Atrium User Manual

Section 4:
SMA Compressed Air Sampler

SMA-316-CA-25

SMA-CA-200

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA Compressed Air Sampler

The SMA Compressed Air/Gas Atrium is used for the quantitative collection of microorganisms that may be present in compressed air and gas lines. The design and construction assures that a sterile test instrument is present to evaluate possible viable contaminants.

The SMA Compressed Air Sampler can be completely sterilized via steam, heat or ETO. Constructed of either 304 or 316L stainless steel, the Atrium is very durable and needs little maintenance. The Atrium is sized at 4 1/2" in diameter by 2 1/2 inches in height. This compact size of the unit provides the opportunity to locate the sampling device where space is limited. The small size of the unit coupled with its simplistic operation has enabled many operations to more accurately report air/gas quality and reduce false positives from operators.

Media Usage and Operation

The unit can be easily and aseptically connected to the desired points of sample by use of sterile 3/8" PVC tubing. Connections are made from the top orifice of the SMA CA Atrium directly to regulated compressed air/gas locations. At a flow rate of 1-2 CFM the unit has been tested and validated to achieve a 95% capture efficiency. Exhaust air is released from underneath the unit directly to the environment without affecting the sample in progress. The SMA CA Atrium uses a 100 mm plate with a media fill of 25 ml. (standard from most suppliers). The use of the SMA 25 ml. fill unit provides the user the ability to sample up to 90 CFM on one agar plate. Airflow regulation can be accomplished either by the installation of a pressure regulator valve at point of sample or by use of the SMA-ROT-SS rotameter. The SMA-ROT-SS Rotameter is attached to the compressed air line prior to sampling and flow regulated from the petcock valve of the compressed air/gas line. Once flow is regulated, the unit is removed and replaced with the SMA-CA Atrium. This assures direct testing of air/gas from the compressed air line to the SMA CA Sampler without the intrusion of the metering device.

SMA Battery Operated Portable Compressed Air Sampler

The SMA Battery Operated Portable Compressed Air Sampler provides calibrated air flow, calibrated memory preset timing, 0.2 micron filtered exhaust, 316L cabinetry, and 4 hour continuous operation. This self-contained unit is an excellent choice for those operations demanding calibrated preset features in a portable compressed air sampler.

Order #	Compressed Air Sampler/Parts Description
SMA-304-CA-25	304 Stainless CA 25 ml. fill level
SMA-316-CA-25	316 Stainless CA 25 ml. fill level
SMA-ROT-SS	Stainless Steel Rotameter
SMA-ROT-STD	Rotameter Stand
SMA-CA200	SMA Portable Compressed Air Sampler

Available Technical Data Supplements (Upon Request)

SMA-4001: SMA Compressed Air Validation Report
SMA-3002: SMA Atrium User Manual

Section 5:
SMA MicroPortable P100 & P200

SMA-P100

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA MicroPortable Viable Air Sampler

The SMA MicroPortable is a rechargeable battery operated microbial air sampler for determining the level of existent viable contaminates in their aseptic manufacturing operations.

The SMA MicroPortable is designed of 316L mirror finished stainless steel. The unit incorporates calibrated air flow, digital readout in cubic feet per minute or liters, 1 CFM (28.3 LPM) and/or 5 CFM (141.5 LPM) flow rates, dual user preset sampling volumes, and filtered exhaust. The unit utilizes the popular SMA Atrium Top that can be completely sterilized via steam, heat or ETO.

The SMA MicroPortable is sized at 10 inches in height by 6 inches in width and weighs only 12 pounds. This unit operates for 8 hours continuously without need for recharging. Recharging of the unit takes approximately 45 minutes and can operate while being recharged. The unit can be located near filling processes or located remotely with the incorporation of the remote sampling probe that can be sterilized prior to use.

Media Usage and Operation

The SMA MicroPortable has been designed to provide a tortuous path that air must travel and assures a 95% capture efficiency of 0.5 micron particles and larger. The integration of multi-orifice top or the remote sampling probe provides the user with the ability to sample for over 120 CFM without agar desiccation. The SMA Atrium uses a media fill level of 25 ml. (standard from most suppliers). The SMA MicroPortable operates by measuring the Cubic Feet or Liters, (dependent on model chosen), that have been sampled. Preset volumes can be programmed and stored into the memory of the counter from 1 Cubic Foot or Liter to 999999 Cubic Feet or Liters. The simple recall of the programmed user preset volumes assures future sampling is done without the need to re-enter sample volumes. Thus, user error is eliminated during the next sample.

Order #	MicroPortable Description
SMAP100-CFM or Liters	CFM or Liter unit with Recharger Kit, Filter Kit, and 1 SMA Sampling Head (5 CFM Flow Rate)
SMAP200-01-CFM or Liters	CFM or Liter unit with Recharger Kit, Filter Kit, and 1 SMA Sampling Head, 1 and 5 CFM Option Flow Rate
SMAP200-02-CFM or Liters	CFM or Liter unit with Recharger Kit, Filter Kit, and 1 SMA Sampling Head, Dual (2) Preset Programmable Volume Feature.
SMAP200-01-CFM or Liters	CFM or Liter unit with Recharger Kit, Filter Kit, and 1 SMA Sampling Head, 1 and 5 CFM Option Flow Rate, and Dual (2) Preset Programmable Volume Feature
SMA-316-TO-25	Additional SMA Multi-Orifice Sampling Head
SMA-316-RE-PROBE	Additional SMA Remote Probe Sampling Head
SMA-503	Additional Recharger (115 V AC or 220 V AC)
SMA-504	Carrying Case
SMA-505	Replaceable Filter Membranes (10)
SMA-506	Disposable Dust Covers (10)
SMA-600	316L Stainless Steel MicroPortable Stand (optional wheels)
SMA-601	Anodized Aluminum MicroPortable Stand (optional wheels)

Available Technical Data Supplements (Upon Request)

SMA-5001: SMA MicroPorable Validation Report
SMA-5002-2: SMA MicroPortable User Manual

Section 6:
SMA Control Centers
1-10 Locations

SMA-CC-1

SMA-CC-2

SMA-CC-3

SMA-CC-5

SMA-CC-10

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA Multi Location Control Centers

The SMA Control Centers are available in two models: The **"EX Model"** Control Center requires the end user to supply a vacuum source either from a central vacuum system or a separate vacuum pump. The **"CC Model"** Control Center is designed and supplied with an external pump (exception to the SMA-CC-1 that incorporates an internal pump). The SMA Control Centers provide calibrated flow regulation, timing and the ability to connect our OneTouch Command System Accessory (specified separately in the pages to follow). The following are brief descriptions of the available SMA Control Centers. (Available in 115 V AC or 220V AC)

SMA-EX-1: The SMA-EX-1 is designed for use with central vacuum systems or external pumps. The unit incorporates 1 rotameter, 1 programmable (memory) timer, and a solenoid in a 316L stainless steel cabinet. The unit is small: 8'L x 8"W x 6"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium.

SMA-CC-1: The SMA-CC-1 is designed for use as a stand-alone unit. The unit incorporates 1 rotameter, 1 programmable (memory) timer, a solenoid, and a 1 CFM pump in a 316L stainless steel cabinet. The unit is small: 16"L x 12"W x 8 1/2"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium.

SMA-EX-2 (no pump) and SMA-CC-2 (includes pump) The SMA-EX-2 and SMA-CC-2 enables 2 location testing simultaneously or independently. The unit incorporates 2 rotameters, 2 programmable (memory) timers and 2 solenoids in a 316L stainless steel cabinet. The unit measures: 16"L x 12"W x 8 1/2"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium. The timers run independently from each other while utilizing a common vacuum source. The SMA-CC-2 unit includes a 3/4 HP pump.

SMA-EX-3 (no pump) and SMA-CC-3 (includes pump) The SMA-EX-3 and SMA-CC-3 enables 3 location testing simultaneously or independently. The unit incorporates 3 rotameters, 3 programmable (memory) timers and 3 solenoids in a 316L stainless steel cabinet. The unit measures: 10"L x 12"W x 10"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium. The timers run independently from each other while utilizing a common vacuum source. The SMA-CC-3 unit includes a 1.0 HP pump.

SMA-EX-5 (no pump) and SMA-CC-5 (includes pump) The SMA-EX-5 and SMA-CC-5 enables 5 location testing done simultaneously. The unit incorporates 5 rotameters, 1 programmable (memory) timer and 1 solenoid in a 316L stainless steel cabinet. The unit measures: 12"L x 17"W x 8 1/2"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium. The timers run independently from each other while utilizing a common vacuum source. The SMA-CC-5 unit includes a 1.0 HP pump.

SMA-CC-10 (includes pump) The SMA-CC-10 enables 10 location testing simultaneously or independently. The unit incorporates 10 rotameters, 10 programmable (memory) timers and 10 solenoids in a 316L stainless steel cabinet. The unit measures: 23"L x 28"W x 22"H. The unit is perfect for ensuring the integration of calibrated time and flow. The unit runs for a specified time period and then automatically turns off the vacuum to the SMA Atrium. The timers run separately from each other while utilizing a common vacuum source. The SMA-CC-10 unit includes a 5 HP pump. This unit is designed to be integrated with our SMA OneTouch System requiring remote location of the control center and pump.

Order#	Description of SMA Control Centers
SMA-EX-1	1 Location EX (without pump) Control Center
SMA-EX-2	2 Location EX (without pump) Control Center
SMA-EX-3	3 Location EX (without pump) Control Center
SMA-EX-5	5 Location EX (without pump) Control Center
SMA-CC-1	1 Location CC Control Center with internal pump
SMA-CC-2	2 Location CC Control Center with external pump
SMA-CC-3	3 Location CC Control Center with external pump
SMA-CC-5	5 Location CC Control Center with external pump (1 timer, 5 rotameters)
SMA-CC-5-5	5 Location CC Control Center with external pump (5 timers, 5 rotameters)
SMA-CC-10	10 Location CC Control Center with external pump

Available Technical Data Supplements (Upon Request)
SMA-3001: SMA Atrium Validation Report

Section 7:
SMA OneTouch
Command System

SMA-OT-02 **SMA-OT-03-2** **SMA-OT-01-3**

SMA OneTouch Command System

The SMA OneTouch Command System moves quantitative microbiological sampling into the future. The SMA OneTouch Command System has been installed and is in operation at many pharmaceutical and biotechnology operations worldwide. This system removes all electronics and vacuum pumps from the aseptic area. The system requires only the OneTouch Remote Start Module (various options) and the SMA Atrium to be placed in the aseptic area. All other components and vacuum pumps are located remotely and controlled remotely from the aseptic area. This system requires hard wiring of both the vacuum tubing and electronic plenum wiring for the OneTouch Point of Sample Boxes. Additionally, VAI has developed an accompanying computer software data base that enables the data transfer of time of sample, sample date, length of sample, sample location, entry results and other features providing the first computer microbial system in the marketplace.

The OneTouch Command System utilizes the SMA Atrium and one of the SMA Control Centers (previously described). Normally the SMA Atrium and SMA Control Centers operate or begin sampling as controlled from the front panel of the SMA Control Center. The OneTouch Command System adds two components to the system, the OneTouch Point of Sample Box and the OneTouch Facility Control Module that remotely starts sampling and eliminates the need to access the control center.

OneTouch Point of Sample Box:

The OneTouch Point of Sample Box is, as the name suggests, the controller that begins sampling at the desired location of the SMA Atrium. The OneTouch Point of Sample Box measures 4" L X 3" W X 3"H. The box contains a system ready light, a sample in progress light, a sample completion light and a reset/operate button. These components are all contained in a 316L mirror finished stainless steel cabinet that is completely sealed for disinfection purposes. This control box signals back to the control center to begin sampling. Upon user prompting, the control center then operates per location for the time period and flow rate that has been preset at the control center. Once time and flow have been initially set, there is no need for resetting the flow and time aspects unless desired sampling time and distance of sample change. The OneTouch Point of Sample Box can be set on surfaces or hard wired to a suitable mounting location on walls, in benches or within the isolator.

OneTouch Facility Control Module:

Operating in the same fashion as the Point of Sample Box, the OneTouch Facility Control Modules are either modular or pre-made as a flush mount unit. These units are accessories that are attached or flush mounted to desired wall locations and can remotely control sampling or are used to view where in the facility sampling is being conducted.

Order #	OneTouch Component Description
SMAOT-01 -# of Locations	SMA OneTouch Modular Wall Control Box
SMAOT-02	SMA OneTouch Point of Sample Box
SMA0T-03-(1,2,3,4,6 or 10)	SMA OneTouch Flush Mount Modules 1, 2, 3, 4, 6, 10 location
SMA-PLTWIRE	Plenum Wiring (ordered and priced per foot)
SMA-VH	HYTREL Vacuum Tubing (ordered and priced per foot)
SMA-0T-0C-1	Single Stainless Outlet Cover w/Fittings (Penetration Kit #1)
SMA-OT-OC-2	Dual Stainless Outlet Cover w/Fittings (Wall Cavity Adapter Kit #1)
SMA-0T-OC-3	Vacuum Outlet Cover w/Fittings (Kit #3)

Available Technical Data Supplements (Upon Request)

SMA-3001: SMA Atrium Validation Report
SMA-6002: SMA Control Center User Manual

How Does the SMA OneTouch Work?

Very simply, one of the VAI Control Centers are chosen based on the number of locations desired to be sampled. The control center and applicable pump are placed outside the clean room area. On the rear of the SMA Control Center is a 9-pin cable connection point. There are three (3) connection points for each location chosen. The plenum wire depicted in the picture below is connected to the rear of the control center and then run to one of the SMA OneTouch Modules. The OneTouch Modules are available in 3 styles. The three types are:

A Point of Sample Style (SMA-OT-02)
A Wall Box Module Style (SMA-OT-1-# of Locations)
A Flush Mount Facility Monitor Style (SMA-OT-03-# of Locations).

These units are now connected to the unit and act as a remote start unit for the control center. At the same time vacuum tubing (SMA-VH) is also run from the control center to the desired point of sample where the SMA Atrium will reside. At this point, both the remote start capabilities and the connection for vacuum for the SMA Atrium are in place. A user has only to touch the "Start" button on the respective SMA OneTouch Module and the control center will start sampling for the preset time period and the preset flow rate. Once the sample is complete, the control center resets itself and awaits the next command.

SMA Plenum Wire and SMA-OT-02 Point of Sample Box

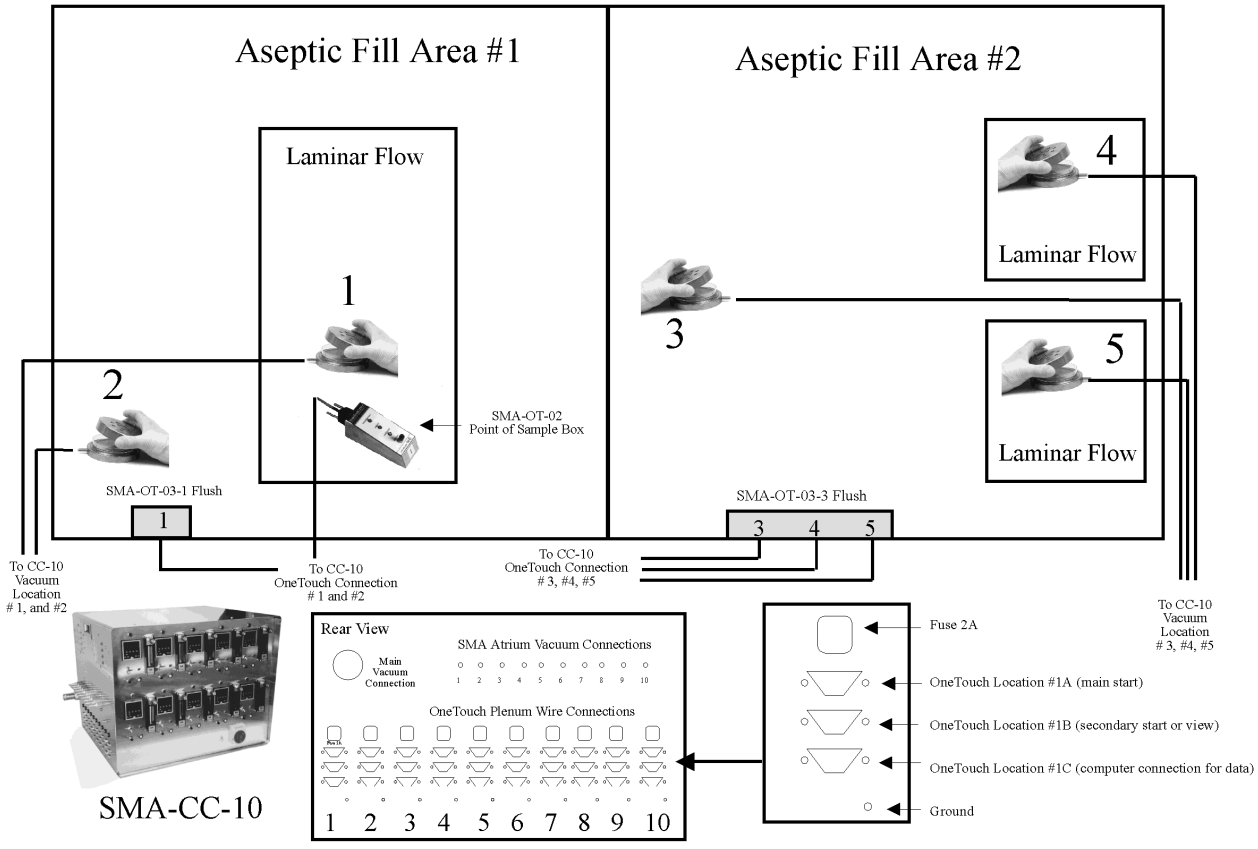
SMA Flush Mount Wall Monitor (SMA-OT-03-2)

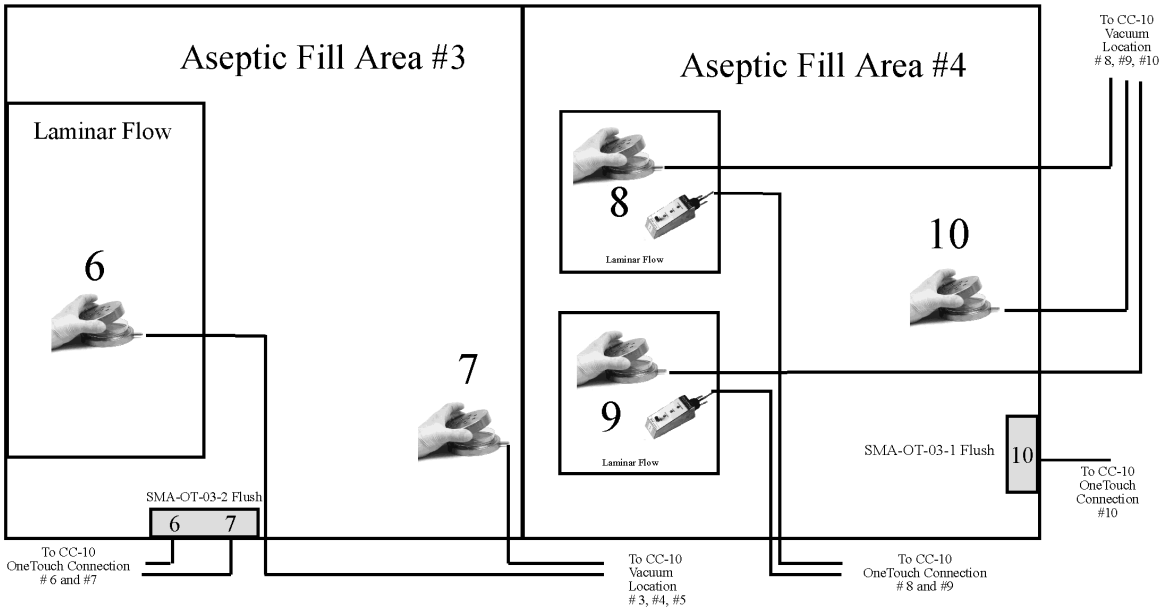
This system removes all the electronics and the pump from the controlled area. It assures the same sample volume and the same sample times are conducted, without exception, each time at the location desired. The system also provides the ability to use one control center to serve various areas. For example, and SMA-CC-10 can sample 2 locations in 5 different areas. This dramatically cuts the costs associated with the purchase of 10 separate microbial air samplers.

The SMA OneTouch System also has accompanying software that will signal back to a computer data base items such as: The time a sample was taken, the date of a sample, the time period sampling was conducted at 1 CFM (or 28.3 LPM), the location of sample, and allow for result entries. This software is presently in validation and is expected for release in June of 1999. However, the system can be purchased and installed and will be computer ready when such software is complete.

SMA OneTouch Command System
Example System Flow Diagram

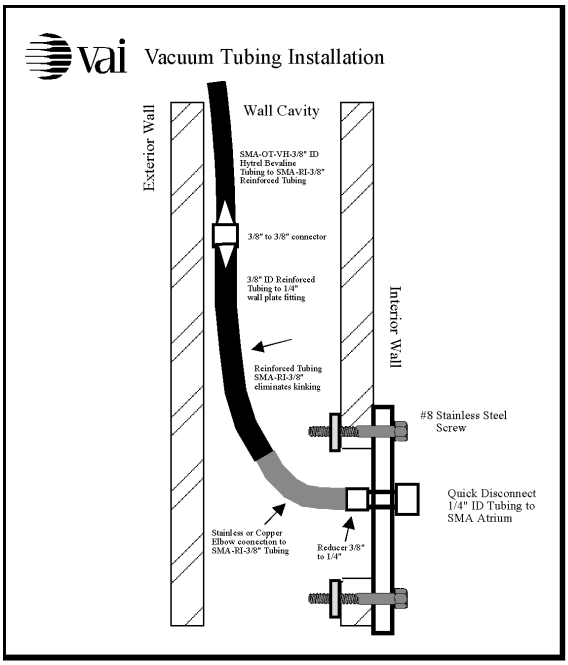
(Flow Diagram utilizes an SMA-CC-10, in separate areas with both Point of Sample Boxes and Flush Mount Modules)

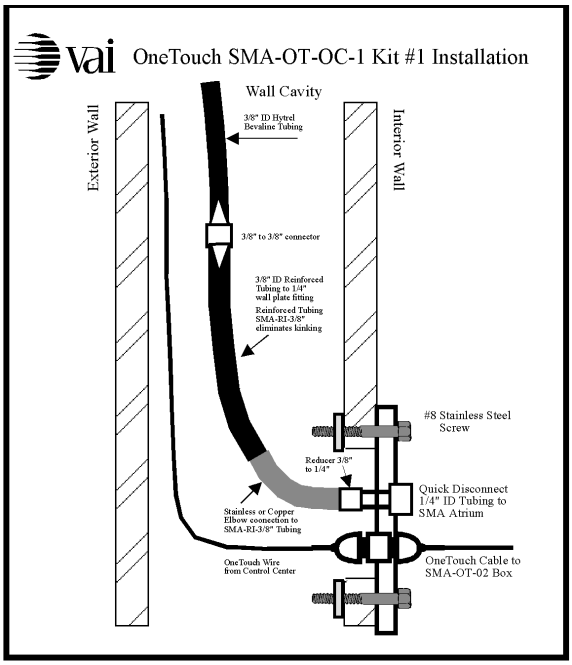


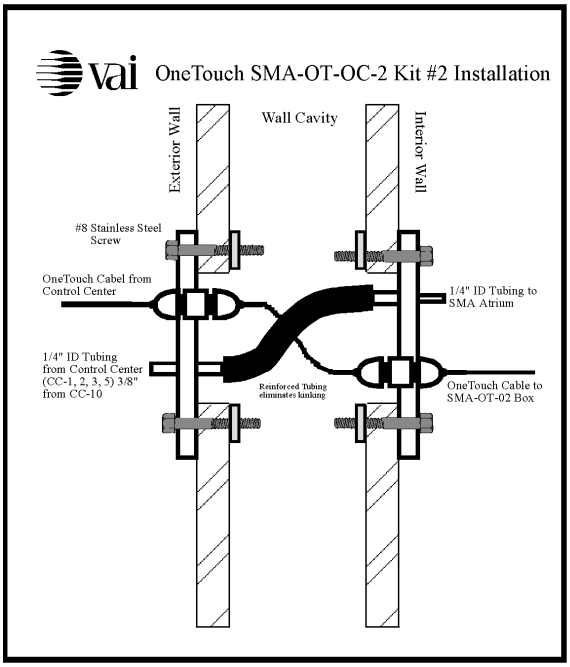


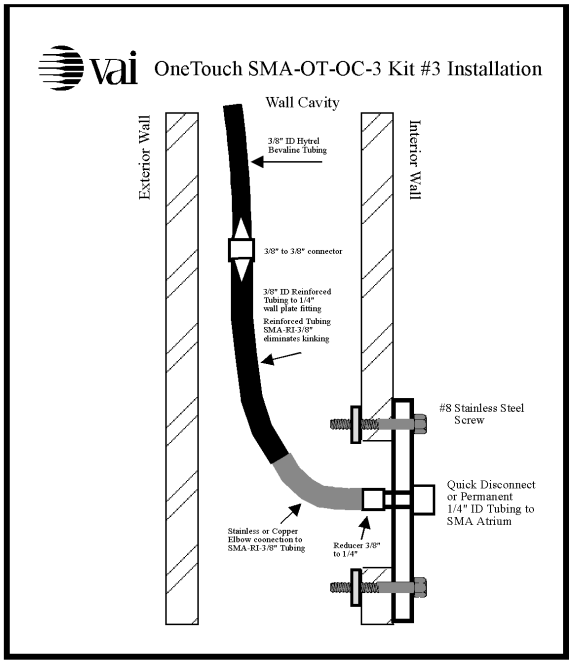
Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

Connections to the Clean Room


Vacuum Tubing Installation
Exterior Wall
Wall Cavity
Interior Wall
SMA-OT-VH-3/8" ID Hytrel Bevaline Tubing to SMA-RI-3/8" Reinforced Tubing
3/8" to 3/8" connector
3/8" ID Reinforced Tubing to 1/4" wall plate fitting
Reinforced Tubing SMA-RI-3/8" eliminates kinking
#8 Stainless Steel Screw
Quick Disconnect 1/4" ID Tubing to SMA Atrium
Stainless or Copper Elbow coonection to SMA-RI-3/8" Tubing
Reducer 3/8" to 1/4"


OneTouch SMA-OT-OC-1 Kit #1 Installation
Exterior Wall
Wall Cavity
Interior Wall
3/8" ID Hytrel Bevaline Tubing
3/8" to 3/8" connector
3/8" ID Reinforced Tubing to 1/4" wall plate fitting
Reinforced Tubing SMA-RI-3/8" eliminates kinking
#8 Stainless Steel Screw
Reducer 3/8" to 1/4"
Quick Disconnect 1/4" ID Tubing to SMA Atrium
Stainless or Copper Elbow coonection to SMA-RI-3/8" Tubing
OneTouch Wire from Control Center
OneTouch Cable to SMA-OT-02 Box

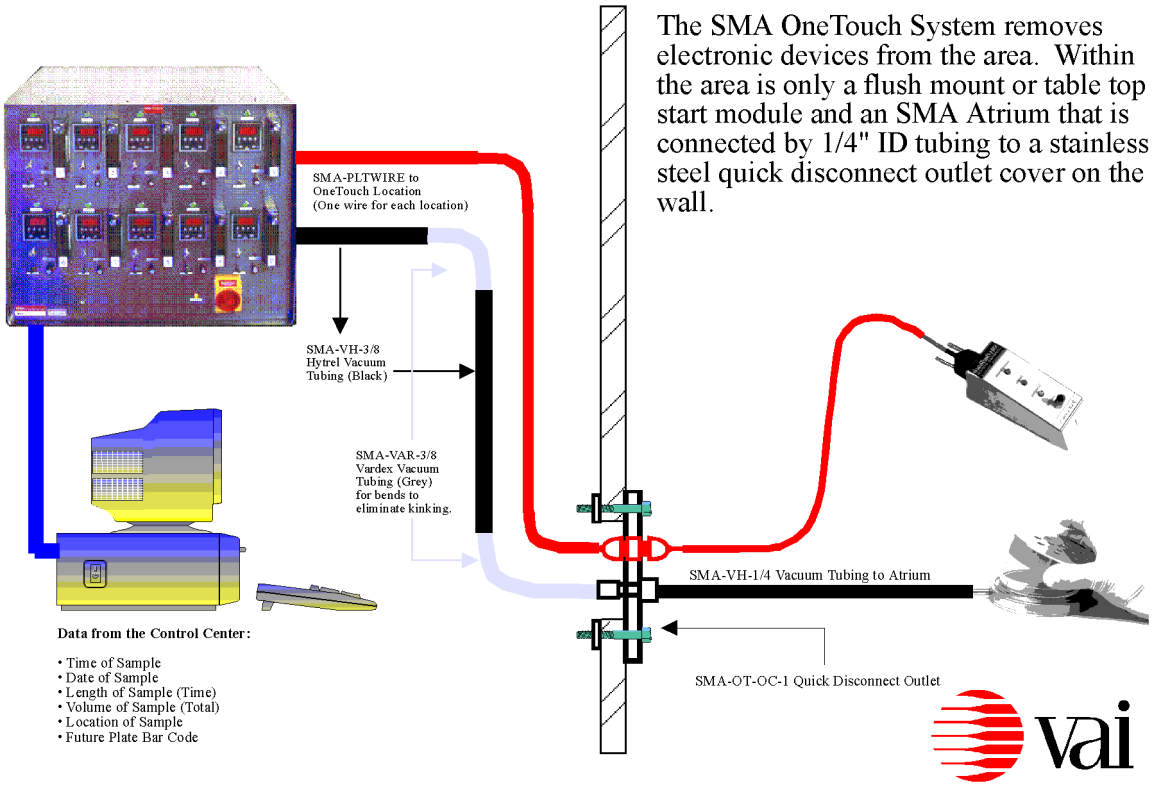

OneTouch SMA-OT-OC-2 Kit #2 Installation
Exterior Wall
Wall Cavity
Interior Wall
#8 Stainless Steel Screw
OneTouch Cabel from Control Center
1/4" ID Tubing to SMA Atrium
1/4" ID Tubing from Control Center (CC-1, 2, 3, 5) 3/8" from CC-10
Reinforced Tubing eliminates kinking
OneTouch Cable to SMA-OT-02 Box


OneTouch SMA-OT-OC-3 Kit #3 Installation
Exterior Wall
Wall Cavity
Interior Wall
3/8" ID Hytrel Bevaline Tubing
3/8" to 3/8" connector
3/8" ID Reinforced Tubing to 1/4" wall plate fitting
Reinforced Tubing SMA-RI-3/8" eliminates kinking
#8 Stainless Steel Screw
Quick Disconnect or Permanent 1/4" ID Tubing to SMA Atrium
Stainless or Copper Elbow coonection to SMA-RI-3/8" Tubing
Reducer 3/8" to 1/4"

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA OneTouch
Microbial Air Sampling System

Table Mount

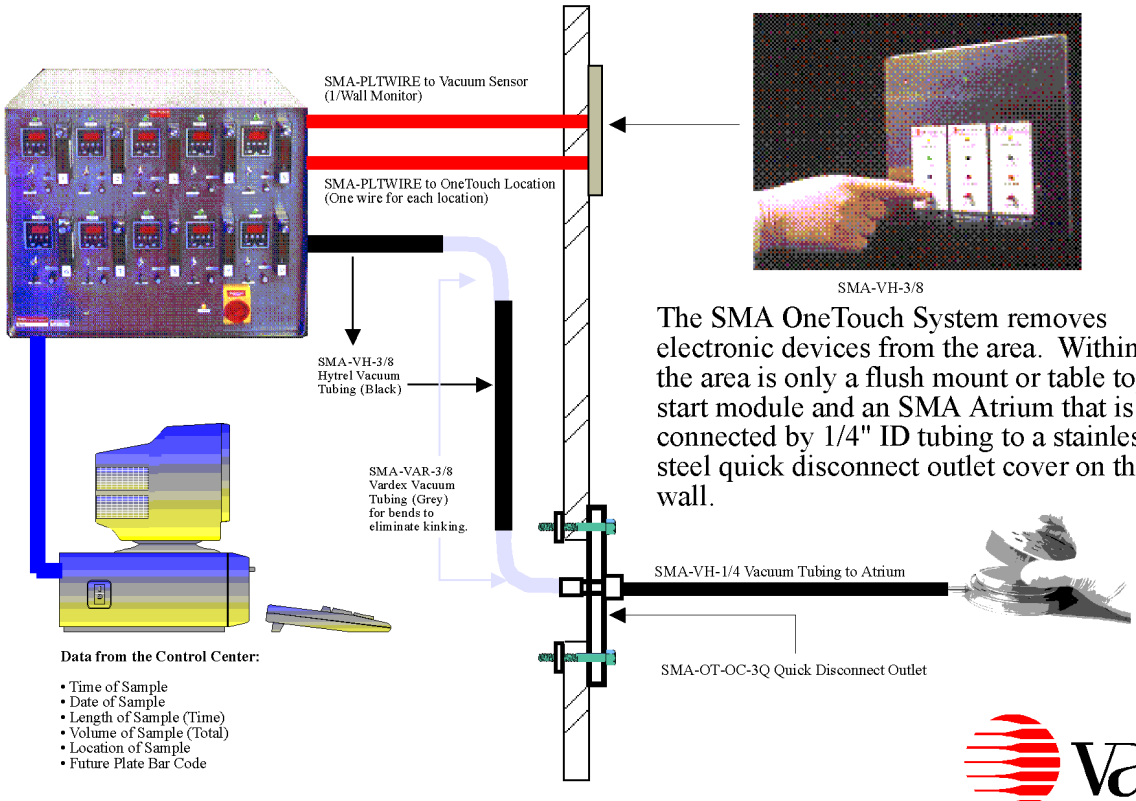


The SMA OneTouch System removes electronic devices from the area. Within the area is only a flush mount or table top start module and an SMA Atrium that is connected by 1/4" ID tubing to a stainless steel quick disconnect outlet cover on the wall.

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

SMA OneTouch Flush Mount

Microbial Air Sampling System



Data from the Control Center:

- Time of Sample
- Date of Sample
- Length of Sample (Time)
- Volume of Sample (Total)
- Location of Sample
- Future Plate Bar Code

The SMA OneTouch System removes electronic devices from the area. Within the area is only a flush mount or table top start module and an SMA Atrium that is connected by 1/4" ID tubing to a stainless steel quick disconnect outlet cover on the wall.

vai

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

Section 8:

SMA ISO-CC Control Centers 1-10 Locations

For Pictures See SMA Control Centers

SMA ISO-CC Microbial Air Sampler

The SMA-ISO feature is an adaptation done to our CC-1, CC-2, CC-3, CC-5 and CC-10 Control Centers. The system design permits the highest level of confidence for sampling within the isolator and assures the non-aspiration or return of possible contaminants from the exterior environment to the isolator or barrier unit.

All VAI "CC" control centers can be adapted to operate in the ISO Mode. Integration of a 2 way solenoid between the rotameter and the SMA Atrium provides the automatic switching of airflow at the completion of sampling from SMA Control Center to the isolator vacuum system. The SMA Control Center Timer is the brains of the system. The timer, once activated, samples from the Atrium through the solenoid to the Rotameter (where volume is gauged) and then proceeds to the control center vacuum pump. Once sampling is complete, the timer signals the solenoid to switch the airflow direction to the isolators central vacuum system (all isolator units incorporate this as a standard feature). This assures that air is always being pulled from the isolator either in a sampling condition or a pause position directing airflow to the isolator vacuum system. This design prevents the return of air into the isolator as flow is always being pulled outward. Alleviating the return of outside air to the isolator system, assures integrity of the environment. The unit is delivered, ready to use with all solenoids contained within the control center. This design also permits continuous sampling to be conducted (up to 3 hours) on one agar plate.

Product Specifications:

Air Flow: 1 CFM
Air Flow Accuracy: +/- 5%
Maximum Sample Volume: 999.99 CFM
Maximum Temperature through Solenoids: 480^{o}F
Connections from Control Center to Atrium = 1/4" NPT
Connection to Isolator Vacuum System: 1/4" NPT
Connections from CC to Pump: SMA-CC-2 (3/8" ID) SMA-CC-3 & 5 (1/2" ID) SMA-CC-10 (1 1/4" ID)
Voltage (CC): 115V AC or 220V AC
Amps: 15A
Calibration: Annual
OneTouch Ready: Yes

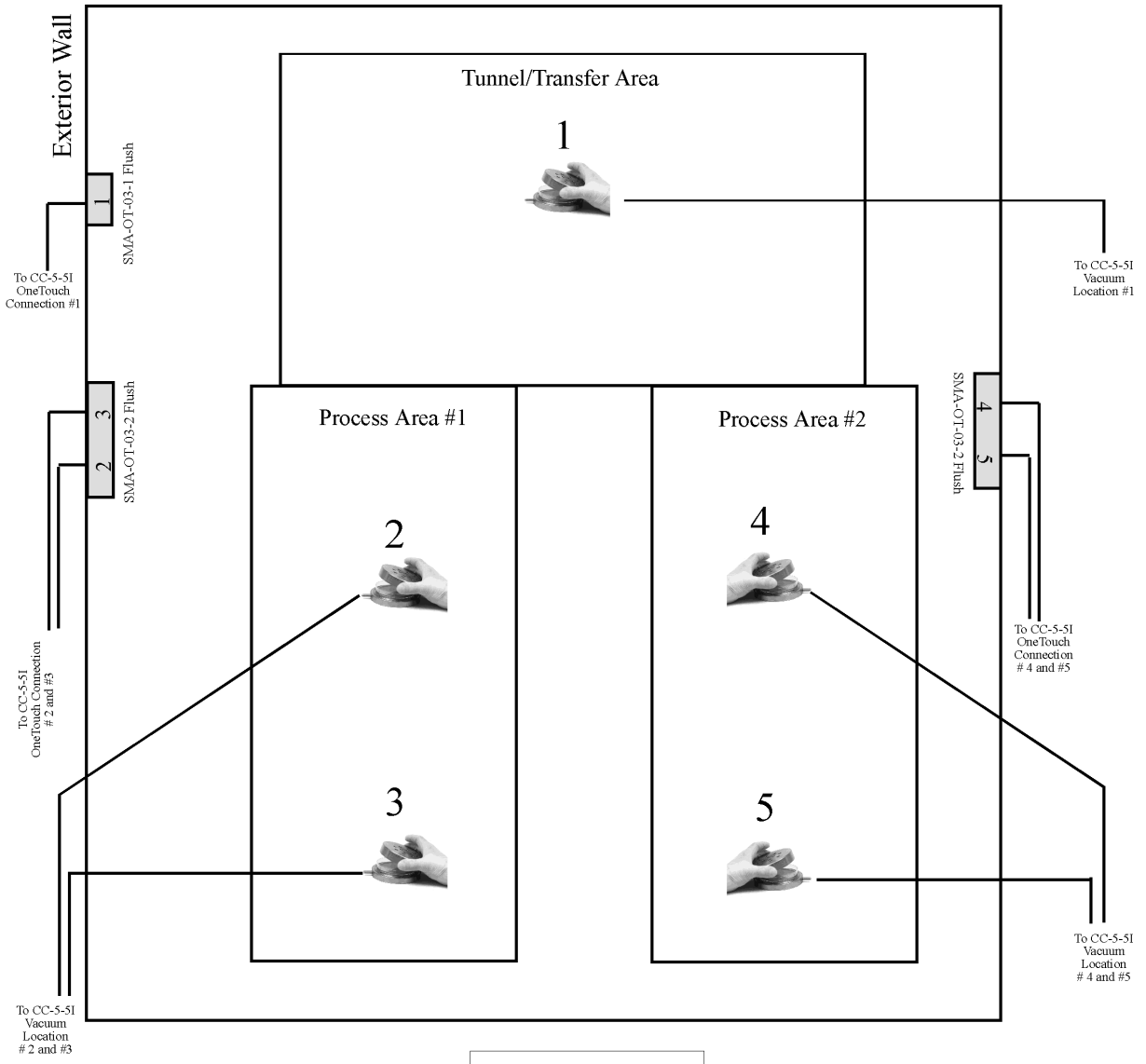
Order #	**Description of ISO Control Centers**
SMA-CC-1I	1 Port Control Center w/internal pump
SMA-CC-2I	2 Port Control Center w/external pump
SMA-CC-3I	3 Port Control Center w/external pump
SMA-CC-5I	5 Port Control Center w/external pump (1 timer, 5 rotameters)
SMA-CC-5-5I	5 Port Control Center w/external pump (5 timers 5 rotameters)
SMA-CC-10I	10 Port Control Center w/external pump

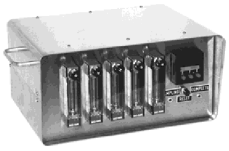
Available Technical Data Supplements (Upon Request)

SMA-3001: SMA Atrium Validation Report
SMA-6002: SMA Control Center User Manual

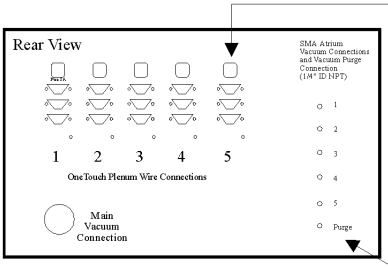
SMA ISO-CC OneTouch Isolator System
Example System Flow Diagram

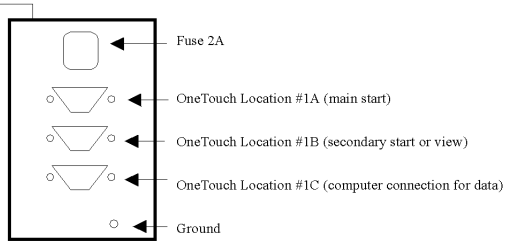
Flow Diagram utilizes an SMA-CC-5-5I with two (2) SMA-OT-03-2's and SMA-OT-03-1 Flush Mount Modules.





SMA-CC-5-5I


Rear View
SMA Atrium Vacuum Connections and Vacuum Purge Connection (1/4" ID NPT)
1 2 3 4 5
OneTouch Plenum Wire Connections
Main Vacuum Connection
Purge


Fuse 2A
OneTouch Location #1A (main start)
OneTouch Location #1B (secondary start or view)
OneTouch Location #1C (computer connection for data)
Ground

The Vacuum Purge Connection is connected to the Isolator Vaccum System. When Sampling is complete, the unit switches vacuum to this location.
Thus, air flow is constantly pulled from the isolator eliminating the possibility of contamination ingress.

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98

Section 9:
Ordering SMA Products

ORDERING INFORMATION

Order#	Description	Orifice Top	Unit Series
Atriums			
SMA-AA-25	Anodized Aluminum SMA	1/2, 1/4, 3/32	Complete Unit
SMA-AA-32	Anodized Aluminum SMA	1/2, 1/4, 3/32	Complete Unit
SMA-AA-B	Anodized Aluminum SMA Bottom	NA	Bottom Only
SMA-AA-T-25	Anodized Aluminum SMA Top	1/2, 1/4, 3/32	Top Only
SMA-AA-T-32	Anodized Aluminum SMA Top	1/2, 1/4, 3/32	Top Only
SMA-304-25	304 Stainless Steel SMA	1/2, 1/4, 3/32	Complete Unit
SMA-304-32	304 Stainless Steel SMA	1/2, 1/4, 3/32	Complete Unit
SMA-304-RE-25	304 Stainless Steel REMOTE SMA	NA	Complete Unit
SMA-304-RE-32	304 Stainless Steel REMOTE SMA	NA	Complete Unit
SMA-304-CA-25	304 Stainless Steel Comp. Air	NA	Complete Unit
SMA-304-CA-32	304 Stainless Steel Comp. Air	NA	Complete Unit
SMA-304-B	304 Stainless Steel SMA Bottom	NA	Bottom Only
SMA-304-T-25	304 Stainless Steel SMA Top	1/2, 1/4, 3/32	Top Only
SMA-304-T-32	304 Stainless Steel SMA Top	1/2, 1/4, 3/32	Top Only
SMA-304-RE-TO-25	304 Stainless Steel REMOTE Top	NA	Top Only
SMA-304-RE-TO-32	304 Stainless Steel REMOTE Top	NA	Top Only
SMA-316-25	316 Stainless Steel SMA	1/2, 1/4, 3/32	Complete Unit
SMA-316-32	316 Stainless Steel SMA	1/2, 1/4, 3/32	Complete Unit
SMA-316-RE-25	316 Stainless Steel REMOTE SMA	NA	Complete Unit
SMA-316-RE-32	316 Stainless Steel REMOTE SMA	NA	Complete Unit
SMA-316-CA-25	316 Stainless Steel Comp. Air	NA	Complete Unit
SMA-316-CA-32	316 Stainless Steel Comp. Air	NA	Complete Unit
SMA-316-B	316 Stainless Steel SMA Bottom	NA	Bottom Only
SMA-316-T-25	316 Stainless Steel SMA Top	1/2, 1/4, 3/32	Top Only
SMA-316-T-32	316 Stainless Steel SMA Top	1/2, 1/4, 3/32	Top Only
SMA-316-RE-TO-25	316 Stainless Steel REMOTE Top	NA	Top Only
SMA-316-RE-TO-32	316 Stainless Steel REMOTE Top	NA	Top Only
SMA-LID	316 Stainless Steel SMA Cover	NA	Lid for SMA
Rotameters		**Specify**	
ROT-AL	Anodized Aluminum ROTAMETER		0-90 SCFH
ROT-SS	Stainless Steel ROTAMETER		0-90 SCFH

ORDERING INFORMATION (cont')

Control Centers

SMA-EX-1	1 LOCATION EX Control Center	115 or 220 V	No Pump
SMA-EX-2	2 LOCATION EX Control Center	115 or 220 V	No Pump
SMA-EX-3	3 LOCATION EX Control Center	115 or 220 V	No Pump
SMA-EX-5	5 LOCATION EX Control Center	115 or 220 V	No Pump
SMA-CC-1	1 LOCATION CC Contro1 Center	115 or 220 V	Includes Pump
SMA-CC-2	2 LOCATION CC Control Center	115 or 220 V	Includes Pump
SMA-CC-3	3 LOCATION CC Control Center	115 or 220 V	Includes Pump
SMA-CC-5	5 LOCATION CC Control Center	115 or 220 V	Includes Pump
SMA-CC-10	10 Port Control Center with Pump Min 208 V AC	208 or 220 V	Includes Pump
SMA-CC-10-SN	Vacuum Sensor 10 PT	115 V	OneTouch Option

SMA MicroPortable

SMAP100-Liter	Portable Unit with Recharger Liter Display	115 or 220 V	Complete Unit
SMAP100-CFM	Portable Unit with Recharger CFM Display	115 or 220 V	Complete Unit
SMAP200-01-CFM	Portable with Reharger and 1 and 5 CFM Flow	115 or 220 V	Complete Unit
SMAP200-03-Liter	Portable with Recharger, 2 User Preset, 28 and 141 LPM Flow	115 or 220 V	Complete Unit
SMAP200-02-CFM	Portable with Recharger and 2 User Preset Volume Selections	115 or 220 V	Complete Unit
SMAP200-01-Liter	Portable with Reharger and 1 and 5 CFM Flow	115 or 220 V	Complete Unit
SMAP200-02-CFM	Portable with Recharger and 2 User Preset Volume Selections	115 or 220 V	Complete Unit
SMAP200-03-CFM	Portable with Recharger, 2 User Preset, and 1 and 5 CFM Flow	115 or 220 V	Complete Unit
SMA-500	Optional P100 Stainless Steel Top Lid		Portable Option
SMA-501	Optional P100 Disposable Dust Covers (10)		Portable Option
SMA-502	Optional P100 Carrying Case		Portable Option
SMA-503	Optional P100 Filter Membranes (10)		Portable Option
SMA-504	Optional P100 Additional Recharger	115 or 220 V	Portable Option

OneTouch System

SMA-OT-01	OneTouch Table Mount Box	OneTouch Box
SMA-OT-02-#	OneTouch Wall Monitor	OneTouch Wall Box
SMA-OT-03-1	Flush Moniotr 1 Location	OneTouch Wall Monitor
SMA-OT-03-2	Flush Moniotr 2 Location	OneTouch Wall Monitor
SMA-OT-03-3	Flush Moniotr 3 Location	OneTouch Wall Monitor
SMA-OT-03-4	Flush Moniotr 4 Location	OneTouch Wall Monitor
SMA-OT-03-6	Flush Moniotr 6 Location	OneTouch Wall Monitor
SMA-OT-03-10	Flush Moniotr 10 Location	OneTouch Wall Monitor
SMA-OT-OC-2	OneTouch Outlet Kit 2	OneTouch Option
SMA-OT-OC-1	OneTouch Outlet Kit 1	OneTouch Option
SMA-OT-PW	Plenum Wire w/connectors	Wire Sold Per Foot
SMA-OT-VH	Hytel Bevaline Tubing	Tubing Sold Per Foot

Veltek Associates, Inc.
1039 West Bridge Street ● Phoenixville, PA 19460-4218
Tel: (610) 983-4949 **Fax:** (610) 983-9494 http://www.sterile.com SMA-98-3 8/27/98